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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,284	07/22/2004	Fabio Rinaldi	27419/150	1852

7590 09/06/2006

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EXAMINER

KOSAR, ANDREW D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/502,284

Applicant(s)

RINALDI ET AL.

Examiner

Andrew D. Kosar

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments and arguments filed June 2, 2006 are acknowledged and have been considered.

The Office action of March 2, 2006 is herein withdrawn in favor of the instant Office Action.

The indicated allowability of claims 2 and 3 is withdrawn for the reasons set forth below.

Specification

The disclosure is objected to because of the following informalities:

The specification does not have a BRIEF DESCRIPTION OF THE DRAWINGS.

The title is awkwardly worded and should be amended.

Appropriate correction is required.

Claim Objections

Claim 10 is objected to for not ending in a period. MPEP § 804.01(m) states that, "Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995)."

Additionally, claim 10 requires 'and' between the last two recited members of the composition.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-4 and 9-11 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 2, 9 and 11 recite “A method comprising administering...” however the claims do not recite for what purpose the method is practiced, i.e. a method for treating hair loss or for reducing hair loss, and thus ‘A method comprising’ is a general utility and does not constitute a substantial, specific or credible utility.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 9 and 11 recite, “A method comprising” however it is unclear and indefinite as to what effect the method is being practiced, e.g. a method for treating hair loss or for reducing hair loss.

Claims 2, 9 and 11 recite, “to combat hair loss” which is vague and indefinite, as ‘combat’ is not defined in the specification such that one would know the metes and bounds of the claims. It is unclear what is, or is not, considered ‘combat’.

Claim 4 recites ‘robust’, which is unclear and indefinite, as the claims and specification do not set forth a definition of ‘robust,’ as it is only found in the headings of the exemplary

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formulations, i.e. Dietetic composition for making the hair robust and reducing hair loss, and one of skill in the art would not know by what standard the hair would be considered 'robust'. For example, does robust mean healthy and strong or thick? Furthermore, 'robust' is a relative term which requires a benchmark by which a comparison can be made.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by RINALDI (F. Rinaldi, et al. Cosmetic Technology (2002) 5,(6), pages 9-15; Abstract cited PTO-892, 3/2/06).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The instant claims are drawn generally to a method comprising administration of a composition comprising spermidine to combat hair loss.

Rinaldi teaches administration of BIOSCALIN[®], which comprises methionine, Vitamins C, E, B6, folate, biotin, calcium pantothenate, Zn, Cu, grape polyphenols and spermidine, to subjects with telogenic defluvium to treat hair loss.

Because the same composition is administered to the same patient population, the telogenic growth is inherently reduced and the hair is inherently 'robust' following administration.

Claims 2-4, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by OTC (“Dietary Supplements market in Italy”; Abstract cited PTO-892, 3/2/06), as evidenced by RINALDI, *supra*.

The instant claims are presented *supra*.

OTC teaches BIOSCALIN[®] as a dietary supplement for anti-aging. Administration would inherently result in ‘robust’ hair and reduced telogenic growth.

Applicant’s have argued that because BIOSCALIN[®] is a brand name, RINALDI “is not sufficient to establish the components of the earlier product,” and that, “Applicant’s believe that the composition of BIOSCALIN was changed to contain spermidine only after the present invention was filed.” (emphasis added; pages 4 and 5, *Remarks*).

Applicant’s arguments have been fully considered, but have not been found persuasive.

Respectfully, it is noted that MPEP § 2145 states, “The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) (“An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness.”).

MPEP § 2112.01 states, “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15

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USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)."

Applicant's 'belief' that the spermidine was not previously present does not constitute evidence as required.

Claims 2-4 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by FALK (US 2003/0118539 A1; cited PTO-892; 3/2/06).

The instant claims are presented *supra*.

The teachings of FALK have been presented previously (Office Action, 3/2/06).

Falk teaches treating or preventing alopecia via administration of polyamine effectors (e.g. claim 26) and specifically teaches spermidine (e.g. paragraph [0173] and Table 1). Falk teaches that the composition can be administered locally or topically as a pharmaceutical (e.g. abstract).

It is noted that defluvium, or effluvium, is the process by which hair is lost in the condition called alopecia, and thus in treating an individual diagnosed with alopecia, one is necessarily treating an individual with telogenic defluvium (or effluvium). As the same composition is administered to the same patient population, one would necessarily have 'more robust' hair and reduce the telogenic phase in the growth cycle.

Claims 2-4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by LARSEN (H.R. LARSEN <http://www.mercola.com/2000/sep/10/milk_cancer.htm>),

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9/10/2000, 6 pages; accessed 9/1/06), as evidenced by SANGUARNSERMSRI (J.

Sanguansermsri and F. Zilliken. Am. J. Clin. Nutr. (1974) 27, pages 859-865).

The instant claims are presented *supra*.

Sanguarnsermsri provides the teachings that spermidine is in milk (throughout).

Larsen teaches that people drink milk, which is a well know practice.

Because the method does not recite the purpose of the method, the patient population claimed is indistinguishable from the general population and nothing precludes administration of the composition to any individual, including the subpopulation of those diagnosed with telogenic defluvium. Thus, in drinking milk one is necessarily consuming a dietary composition comprising spermidine and would inherently have the claimed effects, e.g. robust hair, slow telogenic growth, etc..

Claims 1-4, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by PHILLIPS (B. Phillips. "Myoplex Plus" in Sports Supplement Review. 3rd Edition. (2000), 1 page).

The instant claims are presented *supra*.

Phillips teaches MYOPLEX PLUSTM mixed with milk and 2-4 servings are taken daily.

The composition comprises Vitamins C, E, B₆, B₅ (pantothenic acid) polyphenols (in the form of garcinia camogia flavenoids), zinc, copper, folic acid and biotin. Milk comprises spermidine and methionine. As stated above, administration of the composition would necessarily result in the claimed results, e.g. robust hair, reduced telogenic growth, etc. Because the method does not recite the purpose of the method, the patient population claimed is indistinguishable from the general population and nothing precludes administration of the

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composition to any individual, including the subpopulation of those diagnosed with telogenic defluvium.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-4 and 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-8 of copending Application No. 11/445,776. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the products used in the instant claims, specifically claim 6 of '776 recites the same composition of instant claim 10. Further, the composition of '776 is intended to ‘combat hair loss’, which is the intent of the instantly practiced methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion


It is noted that Applicant's specification teaches that spermidine, "is found in many foods of both animal and plant origin" and thus in eating virtually any meal, one would be consuming a dietary composition comprising spermidine and elicit any claimed benefit, e.g. robust hair, slow telogenic growth, etc.

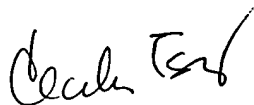
The prior art made of record on the attached PTO-892 and not relied upon in any rejection is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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